

# EXHIBIT CC

**OMNICEF® FOR ORAL SUSPENSION  
T3 COACHING GUIDE**

**ACUTE OTITIS MEDIA and  
PHARYNGITIS/TONSILLITIS**



## OMNICEF® FOR ORAL SUSPENSION T3 COACHING GUIDE FOR ACUTE OTITIS MEDIA AND PHARYNGITIS/TONSILLITIS



### Learning Objectives

- Effectively execute the "One for Both" campaign by:
  - Discussing the pathogen shift in acute otitis media (AOM) and the efficacy of OMNICEF® in patients vaccinated with Prevnar®
  - Discussing the efficacy and compliance factors of OMNICEF and real-world patients with AOM
- Drive the conversion of the 125 mg/5 mL formulation to 250 mg/5 mL formulation for appropriate patients

### Key Messages

#### "One for Both" Campaign

Doctors' chief consideration when treating AOM is choosing a medicine that will treat the infections effectively while patients want a medicine that is easy to take. OMNICEF is the antibiotic that meets both needs.

#### Efficacy Messages

*At least one of the following efficacy messages should be delivered during every call:*

- A clinical study showed the predominant pathogen that causes AOM has shifted from *Streptococcus pneumoniae* to *Haemophilus influenzae*. The percentage of *H influenzae* that is  $\beta$ -lactamase producing has increased while the percentage of *S pneumoniae* that is penicillin susceptible has increased
- OMNICEF provided excellent clinical efficacy vs low-dose amoxicillin/clavulanate for AOM, especially in children vaccinated with the pneumococcal conjugate vaccine
- For the treatment of AOM ... OMNICEF is a guidelines-recommended option, which are based on the opinions and experiences of the authors
- OMNICEF achieves effective concentrations in middle ear fluid to eradicate the pathogens most often implicated in AOM, including *H influenzae* and penicillin-susceptible *S pneumoniae*
- OMNICEF has demonstrated in vitro activity against both  $\beta$ -lactamase-producing and  $\beta$ -lactamase-negative strains

#### Compliance Factor Messages

*At least one of the following compliance factor messages should be delivered during every call:*

- OMNICEF was rated better tasting by children and easier to give by parents vs amoxicillin/clavulanate
- Children preferred the taste of OMNICEF over other often-prescribed antibiotics
- OMNICEF offers additional child- and parent-friendly features (eg, can be taken without regard to food; does not require refrigeration; does not contain aspartame, etc)
- OMNICEF has flexible 5-day BID or 10-day QD dosing for AOM; available as 250 mg/5 mL and 125 mg/5 mL
- OMNICEF was well tolerated with a low incidence of discontinuations due to adverse events in a clinical study vs low-dose amoxicillin-clavulanate



For Representative Education Only

06F-900-P991-1

## OMNICEF® FOR ORAL SUSPENSION T3 COACHING GUIDE FOR ACUTE OTITIS MEDIA AND PHARYNGITIS/TONSILLITIS



### Coaching Strategy: Educating the Representative

- Go after first-line business in pharyngitis/tonsillitis by:
  - Communicating pathogen eradication vs clinical cure
  - Articulating the potential implications of unsuccessful eradication
  - Communicating the factors that may impact antibiotic effectiveness
  - Delivering the OMNICEF "One for Both" messages of efficacy and compliance

### Key Messages: OMNICEF for Pharyngitis

#### "One for Both" Campaign

Doctors' chief consideration when treating AOM is choosing a medicine that will treat the infections effectively while patients want a medicine that is easy to take. OMNICEF is the antibiotic that meets both needs.

#### Efficacy Messages

- There was a difference between clinical cure and bacteriologic cure rates with penicillin in a head-to-head study with OMNICEF
- Infectious Diseases Society of America (IDSA) recommends eradication of the infecting organism to decrease the potential of complications, improve clinical symptoms and signs, and reduce transmission of group A  $\beta$ -hemolytic streptococci
- Failure to eradicate may result in recurrence and higher overall costs due to increased time lost from school and work, more physician visits, and the need for additional prescriptions
- 3 factors that may impact the effectiveness of antibiotic therapy when treating pharyngitis/tonsillitis are: (1) patient compliance, (2) copathogenicity, and (3) activity against protective flora
- OMNICEF has demonstrated superior eradication rates for *Streptococcus pyogenes* and excellent clinical efficacy vs penicillin

#### Compliance Factor Messages

- OMNICEF is easy to take with its kid-preferred taste
- OMNICEF has convenient 10-day QD or 5-day BID dosing in pharyngitis; it has fewer total doses than amoxicillin (Amoxil), amoxicillin-clavulanate (Augmentin), and cephalexin (Keflex)
- OMNICEF offers flexible dosing options as kids grow—125 mg/5 mL, 250 mg/5 mL, and capsules
- The 250 mg/5 mL formulation of OMNICEF offers the same great efficacy in half the volume of the 125 mg/5 mL; it can be used for pediatric patients with pharyngitis who are older and larger



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## OMNICEF® FOR ORAL SUSPENSION COACHING TO CORNERSTONE



	7. OMNICEF® FOR ORAL SUSPENSION	7. OMNICEF® FOR ORAL SUSPENSION
Pre-call	<ul style="list-style-type: none"> <li>Set SMART objectives building on prior calls</li> </ul>	<ul style="list-style-type: none"> <li>Set SMART objectives building on prior calls</li> </ul>
Call	<ul style="list-style-type: none"> <li>Engaged the physician incorporating the "One for Both" theme</li> </ul>	<ul style="list-style-type: none"> <li>Engaged the physician incorporating the "One for Both" theme</li> </ul>
Discussion	<ul style="list-style-type: none"> <li>"Doctor, how has the shift in causative pathogens in AOM affected your treatment decisions?"</li> <li>"Doctor, what has your clinical experience with amoxicillin/clavulanate been?"</li> </ul>	<ul style="list-style-type: none"> <li>"Doctor, how has unsuccessful eradication with penicillin impacted your treatment of pharyngitis/tonsillitis?"</li> <li>"What is an acceptable level of bacteriologic success?"</li> </ul>
Education	<ul style="list-style-type: none"> <li>Discussed pathogen shift in AOM and OMNICEF efficacy in Prevna<sup>®</sup> treated patients</li> <li>Delivered the "One for Both" dual-benefit messages of efficacy and compliance</li> <li>Discussed convenient 250 mg/5 mL formulation</li> </ul>	<ul style="list-style-type: none"> <li>Discussed the efficacy of penicillin</li> <li>Discussed factors that may impact antibiotic effectiveness</li> <li>Discussed convenient 250 mg/5 mL formulation</li> </ul>
Objection Handling	<ul style="list-style-type: none"> <li>Question/Concern: Block data shows OMNICEF vs low-dose Augmentin</li> <li>Response: Study protocol developed in 2002 when physicians assumed Augmentin ES-600<sup>®</sup> would be reserved for persistent recurrent AOM. Broader use since then.</li> <li>Question/Concern: Is the new 250 mg/5 mL formulation too expensive?</li> <li>Response: OMNICEF 250 mg/5 mL is widely covered by managed care plans. Provides added convenience with lower volume. Offer physician coupons. Recap benefits of OMNICEF.</li> </ul>	<ul style="list-style-type: none"> <li>Question/Concern: I'm seeing success with penicillin.</li> <li>Response: While you may be seeing clinical success, there is a chance you're getting bacteriologic failure. IDSA says eradication is critical to decrease potential complications, improve clinical symptoms and signs, and reduce infectivity to close contacts.</li> <li>Question/Concern: OMNICEF is not recommended on the guidelines as is penicillin.</li> <li>Response: Guidelines recommend eradication of the causative pathogen as a goal of therapy. OMNICEF offers superior eradication of <i>S. pyogenes</i> compared with penicillin.</li> </ul>
Call to Action	<ul style="list-style-type: none"> <li>Delivered call to action based on the physician's stage of commitment</li> </ul>	<ul style="list-style-type: none"> <li>Delivered call to action based on the physician's stage of commitment</li> </ul>
Post-call	<ul style="list-style-type: none"> <li>Linked call to prior and next calls</li> <li>Wrote detailed notes soon after call</li> <li>Checked objectives met and set next-call objectives</li> <li>Planned to complete commitments made</li> </ul>	<ul style="list-style-type: none"> <li>Linked call to prior and next calls</li> <li>Wrote detailed notes soon after call</li> <li>Checked objectives met and set next-call objectives</li> <li>Planned to complete commitments made</li> </ul>



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## OMNICEF® CAPSULES

### COACHING TO CORNERSTONE



<b>Pre-call Plan</b>	<ul style="list-style-type: none"> <li>• Beginning in mid-August, plan how to focus the call on AMS.</li> <li>• Plan a transition and deliver a coprimary call about pharyngitis/tonsillitis.</li> </ul>
<b>Open</b>	<ul style="list-style-type: none"> <li>• "Doctor, the last time we spoke, you mentioned that you were beginning to see more cases of AMS."</li> <li>• "Doctor, many physicians are concerned about penicillin failures when treating URTIs."</li> </ul>
<b>Discovery</b>	<ul style="list-style-type: none"> <li>• "Doctor, now that summer is coming to an end, what kinds of respiratory problems are your patients reporting?"</li> <li>• "How are you currently treating your patients with AMS?"</li> <li>• "How do the results of the Henry data comparing OMNICEF to levofloxacin relate to what you are seeing in your practice?"</li> </ul>
<b>Present</b> (refer to core messages)	<ul style="list-style-type: none"> <li>• Include efficacy (POWER) and tolerability (PLAY) on every call.</li> <li>• Discuss convenient dosing.</li> </ul>
<b>Respond</b>	<ul style="list-style-type: none"> <li>• Question/Concern: "I don't think OMNICEF is as powerful as a quinolone. The Henry study doesn't seem believable."</li> <li>• Response: <i>This was a multicenter, randomized, double-blind, noninferiority study with 241 clinically evaluable patients who met stringent inclusion criteria; P values are not statistically significantly different.</i></li> <li>• Question/Concern: "This is not a 'tap' study."</li> <li>• Response: <i>Strict inclusion criteria increases the probability that patients have an acute bacterial infection, rather than an acute viral upper respiratory infection. In fact, the inclusion criteria for this study is one of the benefits of the Henry data. In addition to having at least 2 or more of the signs and symptoms, patients were enrolled in the study based on having radiographic or CT scan evidence of sinusitis. Therefore, symptomology, combined with the radiographic finding, and the duration of symptoms, increases the probability that this study involved patients who truly had bacterial disease.</i></li> <li>• Question/Concern: "This dosing is vs Augmentin XR®, but I don't use Augmentin XR."</li> <li>• Response: <i>OMNICEF is an easy-to-swallow, soft-gel capsule that can be taken without regard to meals and at half the dosing regimen vs Augmentin XR.</i></li> </ul>
<b>Call to Action/Close</b>	<ul style="list-style-type: none"> <li>• Ask for the business!</li> <li>• Deliver an appropriate call to action based on the physician's stage of commitment.</li> </ul>
<b>Transition to Pharyngitis/Tonsillitis</b>	<ul style="list-style-type: none"> <li>• "Doctor, you've already seen the power of OMNICEF in eradicating appropriate pathogens, as well as excellent tolerability in your patients with AMS. You can expect efficacy, tolerability, and easy dosing when using OMNICEF to treat your patients with pharyngitis/tonsillitis."</li> <li>• "Doctor, there may be increasing bacteriologic failures with penicillin; OMNICEF has demonstrated superior eradication of GABHS in tonsillitis."</li> </ul>
<b>Post-call Follow-up</b>	<ul style="list-style-type: none"> <li>• Review transitions to other products presented to the doctor.</li> </ul>

**OMNICEF**  
(cedilux) capsules

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**OMNICEF® CAPSULES COACHING GUIDE****Selling Strategy**

- Reinforce the new campaign for OMNICEF® Capsules (POWERPLAY) by discussing efficacy and tolerability on every call.
- Lead every call with acute maxillary sinusitis (AMS).
- As appropriate, leverage the physician's success with OMNICEF for AMS to grow pharyngitis/tonsillitis business (opportunity call).

**New Campaign:**

Doctors' chief consideration when treating AMS is choosing a medicine that will kill the bacteria that cause AMS, while patients want a medicine that is well tolerated. OMNICEF is the antibiotic that has the POWER to eradicate pathogens and has a tolerability profile that can PLAY well with patients.

**AMS Core Messages****POWER messages—OMNICEF has the POWER to eradicate pathogens:**

*The following efficacy messages should be delivered during every call:*

- Established clinical efficacy comparable to levofloxacin and amoxicillin/clavulanate (Sales Aid pages 2 and 4)
- Effective eradication of common pathogens in AMS (Sales Aid page 8)
- Recommended as a first-line treatment option in treatment guidelines (Sales Aid page 3)

**PLAY messages—OMNICEF has a tolerability profile that can PLAY well with patients:**

*The following PLAY messages should be delivered during every call:*

- More than 29 million OMNICEF prescriptions written since US launch in 1997 (Sales Aid page 5)
- Generally well tolerated
- Low discontinuation rates due to adverse events in clinical trials (Sales Aid page 5)
- Convenient dosing (Sales Aid page 7)
- 87% of managed care patients have full access to OMNICEF (Sales Aid page 9)

**Closing the call with POWER and PLAY messages:**

- On every call, use the back cover of the PowerPlay Sales Aid to drive home the key messages that support OMNICEF as the antibiotic for both efficacy and tolerability

**Pharyngitis/Tonsillitis Core Messages****POWER messages—OMNICEF has the POWER to eradicate pathogens:**

*The following efficacy messages should be delivered during every call:*

- Superior bacterial eradication vs penicillin (Sales Aid page 14)
- Clinical efficacy demonstrated in pharyngitis (Sales Aid page 12)
- Appropriate pathogen coverage

**PLAY messages—OMNICEF has a tolerability profile that can PLAY well with patients:**

*The following PLAY messages should be delivered during every call:*

- OMNICEF had a low discontinuation rate in clinical trials (Sales Aid page 15)
- OMNICEF is a trusted choice, with more than 29 million prescriptions since 1997 (Sales Aid page 15)
- OMNICEF is eliminated principally by the kidneys, not appreciably metabolized in the liver (Sales Aid page 15)
- Pregnancy category B (Sales Aid page 15)

**OMNICEF**  
(ceftriaxone) capsules

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06F-900-P992-1

**Card #1**

Dr. Taylor: "Your information shows OMNICEF vs. low-dose Augmentin. I use Augmentin ES because I feel that it is more effective against H.flu."

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make it  
**COUNT**

06C-900-0995-1



"Doctor you are correct, the Block study evaluated low-dose Augmentin and not high-dose Augmentin ES. As the study protocol was being developed in 2002, Augmentin ES had only been available for a short period. At that time, the thought leader community and pediatricians thought the drug would be reserved for its narrow indication of persistent recurrent AOM. Therefore, this study was designed using OMNICEF vs low dose Augmentin. With time, they have noted a broader use of Augmentin ES. Due to the robust set of OMNICEF comparative data versus low dose Augmentin, Abbott is sponsoring a head to head clinical study of OMNICEF and Augmentin ES. And, in a study 9 out of 10 kids preferred the taste of OMNICEF."

Material(s):  
Core Visual Aid

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**Card #2**

Dr. Singh: "I know that OMNICEF Oral Suspension is  
now available in a 250mg/5mL formulation.  
But, isn't it very expensive for patients?"

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EDUCATION ONLY**

**make it  
COUNT**

06C-900-0995-1

"Doctor, remember that OMNICEF Oral Suspension is widely covered on national managed care plans. So, cost may not be of concern for many of your patients. Keep in mind that the 250mg/5mL formulation of OMNICEF Oral Suspension has patient- and parent-friendly features as well as the efficacy that you have come to trust in half the volume of medication." In addition, it has great strawberry taste.

Material(s):  
Coupons  
Core Visual Aid

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### **Card #3**

Dr. Bugbee: "Why should I be concerned about the rise in *H. flu*? The Hib vaccine helps protect my patients from AOM due to *H.flu* infection."

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EDUCATION ONLY

make it  
**COUNT**

06C-900-0995-1

"Doctor, I understand the Hib vaccine helps to protect against *H. flu* type B, also known as *typeable H. flu*. Hib does not offer coverage for non-typeable *H. flu*, however. It's this non-typeable *H. flu* that causes AOM. OMNICEF is an extended-spectrum cephalosporin with excellent gram + and – coverage which provides confidence for your empiric treatment of AOM. And, in a study 9 out of 10 kids preferred the great strawberry taste of OMNICEF."

Material(s):  
Core Visual Aid

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**OMNICEF.**  
(ceftriaxone) for oral suspension  
125mg/5mL and 250mg/5mL

06C-900-0995-1

**Card #4**

**OMNICEF causes red stool and cannot be dosed with  
iron-fortified infant formula.**

**FOR REPRESENTATIVE  
EDUCATION ONLY**

**make it  
COUNT**

06C-900-0995-1

"Doctor, some patients who take OMNICEF may experience discolored stools. This discoloration might be red, berry, pink, or rust in color. It is caused by a non-absorbable complex between OMNICEF or its breakdown products and iron in the GI tract. This reddish discoloration is due to the combination of iron and OMNICEF and is not dangerous and not a cause for concern. During the US premarketing clinical trials 0.2% of patients reported abnormal stools.

Regarding iron-fortified infant formula, OMNICEF may be administered because there is no significant effect to the pharmacokinetics of OMNICEF.

Regarding iron supplements, OMNICEF should be administered two hours before or two hours after the iron.

And lastly, in clinical trials for Augmentin, 3% of patients discontinued therapy because of drug-related events. In clinical trials for OMNICEF, 3% of adult and adolescent patients discontinued medication due to adverse events, primarily for gastrointestinal disturbance."

Material(s): Abbott PI

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## **Card #5**

**Dr. Jeffries runs a large, busy pediatric practice. His highest priority when prescribing is efficacy. He wants to feel confident that 5-day OMNICEF Oral Suspension will work as well as other competing antibiotic therapies in treating acute otitis media.**

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EDUCATION ONLY**

**make it  
COUNT**

**06C-900-0995-1**



"Doctor, in a study comparing 5-day OMNICEF to 10-day Augmentin, OMNICEF demonstrated comparable clinical efficacy. In the same study, OMNICEF demonstrated statistically significantly higher cure rates than Augmentin for Prevnar-vaccinated patients 6 months to 2 years old. These data show that OMNICEF provides an effective short course therapy for your pediatric patients. As you may know, AOM is diagnosed most often in children less than 2 years of age. Today's kids need a medication that works, and OMNICEF works against today's pathogens.

And, great strawberry taste is a plus."

Material(s):

Core Sales Aid

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**Card #6**

**Dr. Trammel: "Will my patients like the  
taste of OMNICEF?"**

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**make it  
EASIER**

06C-900-0995-1

"Doctor, in a single-center panel assessment by healthy volunteers aged 4 to 8 years, respondents surveyed rated the taste of OMNICEF Oral Suspension 125 mg/5mL as preferred vs. amoxicillin/clavulanate, azithromycin, and cefprozil. In short, OMNICEF delivered the taste kids preferred. And, OMNICEF has demonstrated statistically higher cure rates vs. amoxicillin/clavulanate in Pneumococcal conjugate vaccinated patients 6 months to 2 years old."

Material(s):  
Core Visual Aid  
AMS Flashcard

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### **Card #7**

Dr. Smith is a well respected small-town pediatrician who has been treating AOM with amoxicillin for nearly 30 years. He's read about the pathogen shift but not sure how OOS will perform given the shift.  
What can you say that will change his mind?

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EDUCATION ONLY**

**make it  
COUNT**

06C-900-0995-1

"Doctor, the more common bacterial pathogens causing AOM are different ones today than they used to be. Pneumococcal conjugate vaccine has shifted the pathogens causing AOM. Beta-lactamase producing *H influenzae* is the predominant pathogen in AOM today. Just as pathogens have changed, so have choices for treatment of AOM. In a recent study, OMNICEF showed in vitro activity against *H influenzae*. In a study comparing 5-day OMNICEF to 10-day Augmentin, OMNICEF demonstrated comparable clinical efficacy. In the same study, OMNICEF demonstrated statistically significantly higher cure rates over Augmentin for Prevnar-vaccinated patients 6 months to 2 years old. Today's kids need a medication that works, and OMNICEF works against today's pathogens."

Material(s):  
Core Sales Aid

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**Card #8**

**Dr. Lehman prescribes OMNICEF for his pediatric patients with AOM, but was not aware of OMNICEF in treating AMS.**

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EDUCATION ONLY**

**make it  
COUNT**

06C-900-0995-1

"Doctor Lehman, as you may know, sinusitis is closely linked to acute otitis media. The Eustachian tube connects the middle ear cavity via the nasopharynx, and the same pathogens that cause AOM also cause AMS. In a AMS study of patients 13 years of age and older comparing the efficacy of OMNICEF Capsules QD and BID to amoxicillin/clavulanate TID, OMNICEF demonstrated excellent efficacy. If you trust OMNICEF for AOM, you will trust it for the treatment of AMS.

Not only was OMNICEF effective, but it was also well tolerated. In the same study I just mentioned, only 1% of 582 patients taking OMNICEF QD and 3% of patients taking OMNICEF BID discontinued OMNICEF because of adverse events, compared to 5% of the 603 patients in the Augmentin group."

Material(s):  
AMS Flashcard

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### **Card #9**

Dr. Aronson is a high-potential physician who currently prescribes Augmentin for her AMS patients. She hasn't prescribed OMNICEF because she's not sure how it stacks up against the other antibiotics on the market.

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**make it  
COUNT**

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"Dr. Aronson, OMNICEF provides excellent efficacy for AMS. A study by Gwaltney et al. demonstrated excellent clinical response rates for AMS versus amoxicillin/clavulanate in the treatment of acute community-acquired bacterial sinusitis in patients 13 years of age or older. If you are comfortable with the efficacy of OMNICEF in AOM, you'll feel confident in prescribing AMS. And, in a study 9 out of 10 kids preferred the taste of OMNICEF over Augmentin and Cefzil."

Material(s):  
AMS Flashcard

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**Card #10**

**Dr. Buckley: "I don't use OMNICEF because I am  
concerned about atypicals."**

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EDUCATION ONLY**

**make it  
COUNT**

06C-900-0995-1

"Doctor, I understand your concern, however, according to the Sanford Guide and a recent study by Drs. Casey and Pichichero, atypical pathogens are not the main pathogens responsible for causing acute otitis media. The evidence and guidelines support OMNICEF as an appropriate first line treatment option for acute otitis media. Therefore, you can have confidence that OMNICEF can provide effective treatment.

And, OMNICEF was not only effective, it was also well tolerated. In a recent study OMNICEF had fewer discontinuations due to adverse events than Augmentin. Only 1% of 582 patients taking OMNICEF QD and 3% of patients taking OMNICEF BID discontinued OMNICEF because of adverse events, compared to 5% of the 603 patients in the Augmentin group.

And lastly, in clinical trials for Augmentin, 3% of patients discontinued therapy because of drug-related events. In clinical trials for OMNICEF, 3% of adult and adolescent patients discontinued medication due to adverse events, primarily for gastrointestinal disturbance."

Material(s):  
Core Sales Aid

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**Card #11**

**Dr. Stevens: "I won't use OMNICEF in  
penicillin-allergic patients."**

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EDUCATION ONLY**

**make it  
COUNT**

06C-900-0995-1

"Doctor, I understand your concern. Please call our Medical Information at 1-800-633-9110 to further discuss this issue."

Material(s):  
Fast Fax

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**Card #12**

Dr. Fishman: "I think of OMNICEF Oral Suspension as a  
3<sup>rd</sup> generation cephalosporin with less effective  
gram-positive pathogen coverage."

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EDUCATION ONLY**

**make it  
COUNT**

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"Doctor, OMNICEF Oral Suspension is an extended spectrum cephalosporin with coverage of gram positive and gram negative pathogens that commonly cause acute otitis media. OMNICEF Oral Suspension achieved middle ear fluid concentrations up to six times the MIC of H.flu and 12 times the MIC of S. pneumoniae, making it a choice for the empiric treatment of acute otitis media. OMNICEF Oral Suspension is also a guideline recommended first line option for acute otitis media treatment because of its pathogen coverage, including penicillin susceptible Streptococcus pneumoniae.

Also, in a study 9 out of 10 kids preferred the taste of OMNICEF."

Material(s):  
Core Visual Aid

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